



פברואר 2021

רופא/ה, רוקח/ת נכבד/ה, ברצוננו להודיעך על עדכון בעלון לרופא ולצרכן עבור:

**IXIFI 162-94-35522-00**

### **אִיקְסִיפִי**

#### **Indicated for :**

##### Adult Crohn's disease

IXIFI is indicated for treatment:

- of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.
- treatment of fistulising, active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy).

##### Ulcerative colitis

•IXIFI is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6 mercaptopurine (6 MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

##### Rheumatoid arthritis

IXIFI, in combination with methotrexate, is indicated for the reduction of signs and symptoms as well as the improvement in physical function in:

- adult patients with active disease when the response to disease modifying antirheumatic drugs (DMARDs), including methotrexate, has been inadequate.
- adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs.

In these patient populations, a reduction in the rate of the progression of joint damage, as measured by X ray, has been demonstrated.

##### Ankylosing spondylitis

IXIFI is indicated for treatment of severe, active ankylosing spondylitis, in adult patients who have responded inadequately to conventional therapy.

##### Psoriatic arthritis

IXIFI is indicated for treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate.

\* IXIFI should be administered:

- in combination with methotrexate
- or alone in patients who show intolerance to methotrexate or for whom methotrexate is contraindicated.

Infliximab has been shown to improve physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X ray in patients with polyarticular symmetrical subtypes of the disease.

##### Psoriasis

IXIFI is indicated for treatment of moderate to severe plaque psoriasis in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen ultra-violet A (PUVA)

**להלן העדכונים העיקריים בעלון לרופא:****4.8 Undesirable effects***Neoplasms benign, malignant and unspecified (including cysts and polyps)*

- Rare: Lymphoma, non-Hodgkin's lymphoma, Hodgkin's disease, leukaemia, melanoma, cervical cancer.
- Not known: Hepatosplenic T-cell lymphoma (primarily in adolescents and young adult males with Crohn's disease and ulcerative colitis), Merkel cell carcinoma, **Kaposi's sarcoma.**

*Nervous system disorders*

- Very common: Headache.
- Common: Vertigo, dizziness, hypoesthesia, paraesthesia.
- Uncommon: Seizure, neuropathy.
- Rare: Transverse myelitis, central nervous system demyelinating disorders (multiple sclerosis-like disease and optic neuritis), peripheral demyelinating disorders (such as Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy and multifocal motor neuropathy).
- Not known: Cerebrovascular accidents in close temporal association with infusion.**

**Infusion-related reactions**

In post-marketing experience, cases of anaphylactic-like reactions, including laryngeal/pharyngeal oedema and severe bronchospasm, and seizure have been associated with infliximab administration (see section 4.4). Cases of transient visual loss occurring during or within 2 hours of infliximab infusion have been reported. Events (some fatal) of myocardial ischaemia/infarction and arrhythmia have **been reported, some in close temporal association with infusion of infliximab; cerebrovascular accidents have also been reported** in close temporal association with infusion of infliximab.

**להלן העדכונים העיקריים בעלון לצרכן:****4. תופעות לוואי**

**סימנים של בעיות במערכת העצבים (כולל בעיות בעיניים) כגון פרכוסים סימנים של שבץ (חוסר תחושה פתאומי או חולשה בפנים, בזרוע או ברגל, במיוחד בצד אחד של גופך; בלבול פתאומי, בעיות דיבור או הבנה; בעיות ראייה בעין אחת או בשתי העיניים, בעיות הליכה, סחרחורת, אובדן שיווי משקל או תיאום (קואורדינציה) או כאב ראש חמור), פרכוסים, עקצוץ / אדנטיזם חוסר תחושה בחלקי גוף שונים או חולשה בזרועות או ברגליים, שינויים בראייה כגון ראייה כפולה או בעיות עיניים אחרות.**

העלונים נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:

<http://www.health.gov.il/units/pharmacy/trufot/index.asp>

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת: פייזר פי אף אי פרמצבטיקה ישראל בע"מ

רח' שנקר 9, ת.ד. 12133, הרצליה פיתוח, 46725

בכבוד רב,  
אורטל עבדי  
רוקחת ממונה